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## Brazil

## Food and Agricultural Import Regulations and Standards

## Country Report

## 2004

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**Report Highlights:**

This report outlines the requirements for food and agricultural imports for Brazil. All sections in this report have been update to reflect changes implemented by the Brazilian government as of July 28, 2004.

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Includes PSD Changes: No  
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**DISCLAIMER:** the Office of Agricultural Affairs (OAA) of the USDA/Foreign Agricultural Service in Brasilia, Brazil has prepared this report for U.S. exporters of domestic food and agricultural products. While every possible care has been taken in the preparation of this report, information provided may not be completely accurate either because policies have changed since its preparation, or because clear and consistent information about these policies were not available. It is highly recommended that U.S. exporters verify the full set of import requirements with their foreign customers, who are normally best equipped to research such matters with local authorities, before any goods are shipped. FINAL IMPORT APPROVAL OF ANY PRODUCT IS SUBJECT TO THE IMPORTING COUNTRY'S RULES AND REGULATIONS AS INTERPRETED BY BORDER OFFICIALS AT THE TIME OF PRODUCT ENTRY. Please contact this office, if you have any comments, corrections or suggestions about the material contained in this report. Our telephone, fax, and e-mail address are provided at the end of this report.

## I. FOOD LAWS

Brazil is a federated republic composed of 26 states plus the Federal District, with three levels of government: federal, state and municipal; similar to the United States' governmental structure. Food regulations issued at the federal level are contained in various types of legal documents (Laws, Decrees, Executive Orders, Directives, Circulars, Resolutions, Provisional Measures) and to become official, or in order to be implemented, must be published in Brazil's *Diario Oficial* (similar to the U.S. Federal Register).

Brazil is a member of the World Trade Organization (WTO) and therefore has made commitments to subscribe to the Sanitary and Phytosanitary (SPS) Agreement, and to the underlying Codex Alimentarius (CODEX) principles. State and municipal governments also have the authority to regulate and enforce state and municipal laws. Legally, federal regulations must be followed when there are conflicts between federal-state-municipal level legislation, as well as conflicts between Ministries within the federal level.

In the federal government numerous agencies within several Ministries share jurisdiction in ensuring the safety of the Brazilian food supply, and regulate imports of all agricultural commodities and foods. In general, the Ministry of Agriculture, Livestock, and Food Supply (MAPA) is the primary Ministry which oversees and enforces most of the regulations regarding the production, marketing, import and export of *fresh and semi-processed* agricultural and food products.

The Ministry of Health (MS) is the primary Ministry, which enforces most of the regulations regarding *processed* food products, regardless of its origin, and in this area has similar functions in regulating food as does the Food and Drug Administration (FDA) in the United States.

Other Ministries and/or agencies also involved in some aspects of food safety are the Environment Protection Institute (IBAMA), within the Ministry of the Environment; The National Institute of Metrology, Standardization and Industrial Quality (INMETRO), within the Ministry of Development, Industry and Commerce (MDIC); the National Technical Commission on Biosafety (CNTBio), which is an inter-Ministerial Commission but based in the Ministry of Science and Technology (MCT); and the Department of Consumer Protection and Defense (DPDC) within the Ministry of Justice.

**Ministry of Agriculture, Livestock, and Food Supply (MAPA)**

The Brazilian Ministry of Agriculture, Livestock, and Food Supply (MAPA) is composed of four major offices, called Secretariats: the Office of Agricultural Policy (SPA), the Office of Rural Development and Cooperatives (SARC), the Office of Agricultural Production and Marketing (SPC) and the Office of Agricultural Protection (SDA). MAPA's regulatory activities of interest for this report are primarily enforced by SDA, and to a lesser extent by SARC.

**1. Office of Agricultural Protection (SDA):**

The Office of Agricultural Protection is responsible for enforcing regulations governing domestic and imported plants and animals, and their respective products and by-products, and certain other agriculturally related products. In cooperation with State governments, SDA administers Federal laws and regulations, and coordinates the Brazilian government's positions in international forums, such as the World Trade Organization (WTO), Office of International Epizootic (OIE), International Plant Protection Committee (IPPC), and Codex Alimentarius (CODEX). SDA is composed of main three Departments, and one major coordinating office for inspection at airports and ports in Brazil called VIGIAGRO.

- The Department of Animal Origin Products Inspection Service (DIPOA),
- The Department of Animal Health (DDA), and
- The Department of Plant Health and Inspection Service (DDIV).

**1.1. Department of Animal Origin Products Inspection Service (DIPOA).**

DIPOA is responsible for ensuring that all products of "animal origin" (meat derived from cattle, sheep, swine, goats, horses, game meat, poultry, dairy products, eggs, and seafood) moving in interstate and foreign commerce are safe, wholesome for consumption, and accurately labeled. DIPOA's regulatory responsibilities are similar to those ascribed in the United States to USDA's Food Safety Inspection Service (FSIS) for meat and meat products, and to USDA's Agricultural Marketing Service (AMS) for dairy products and eggs, as well as those of the U.S. Department of Health and Human Services' (HHS) Food and Drug Administration (FDA) and the U.S. Department of Commerce's (USDOC) National Oceanic and Atmospheric Administration, National Marine Fisheries Services (NOAA/NMFS) for seafood products. DIPOA is also the federal agency responsible for enforcing federal regulations regarding the Hazard Analysis Critical Control Points (HACCP) for the meat, dairy, and seafood industries.

Both domestic and foreign producers of meat and meat by-products, milk and milk by-products, and seafood sold in Brazil must be registered with SDA/DIPOA. In order to export these animal products of animal origin to Brazil, the exporting country's inspection system must first be recognized by DIPOA as "equivalent" to the Brazilian system. In order for this to happen the appropriate regulatory authorities of the exporting country must fill out a questionnaire and include all the regulations concerning inspection of meat products in that country. On the basis of responses in the questionnaire, Brazilian authorities will judge if the inspection system of that country provides an equivalent level of protection to the Brazilian system. Random on-site visits to a sample group of processing plants will be conducted in order to verify the accuracy of the responses to the questionnaire.

DIPOA will then issue a list of approved plants eligible to export meat and meat by-products to Brazil. Any future inclusion of meat plants in this list must be requested by the proper federal authority within the exporting country through their respective Embassies in Brasilia. The United States inspection system for products of animal origin has been officially recognized by DIPOA as "equivalent" to the Brazilian system.

The major laws and regulations that provide DIPOA's regulatory authority for domestic and imported products of animal origin are:

- \* Decree 30,691 of March 29, 1952
- \* Ministerial Directive 574 of December 8, 1998
- \* SDA Directive 183 of October 9, 1998
- \* DIPOA Resolution Number 1 of January 21, 1999
- \* Ministerial Directive 46 of February 10, 1998

Note: Brazilian federal regulations can be found in the home page of the Diario Oficial (Brazil's Federal Register): <http://www.in.gov.br>

### 1.2. Department of Animal Health - DDA

DDA is responsible for enforcing regulations governing the import and the export of live animals, semen and embryos, as well as the registration of veterinary products. In cooperation with State governments, DDA enforces federal laws and regulations to protect and improve animal health, control and eradicate animal diseases (such as the Foot-and-Mouth Disease Eradication Program). It defends Brazilian borders against foreign and exotic animal diseases. In this respect, DDA's regulatory responsibilities are similar to those ascribed in the United States to the USDA's Animal and Plant Health Inspection Service's (APHIS), Veterinary Services (VS).

In addition, DDA is also responsible for the registration and regulation of veterinary products used in the animal industry. In this regard, its regulatory responsibilities are similar to those ascribed in the United States to HHS/FDA's Center for Veterinary Medicine as well as to APHIS Veterinary Biologics.

In order to export live animals, semen and embryos to Brazil, exporters of U.S. genetics must meet the animal health requirements issued by DDA, which can be seen on APHIS/VS's home page <http://www.aphis.usda.gov>. Several of these requirements were updated recently to include restrictions on imports of animal genetics and animal by-products in view of the BSE outbreak in the United States.

DAA also is responsible for enforcing the National Program for Controlling Biological Residue in Meats through their Animal Reference Laboratories.

The major laws and regulations that provide DDA's regulatory authority for domestic and imported animal genetics and veterinary products are:

- \* Decree 24,548 of July 3, 1934
- \* Decree 64,499 of May 14, 1969

Note: Brazilian federal regulations can be found in the home page of the Diario Oficial (Brazil's Federal Register): <http://www.in.gov.br>

Notes: As of July 2000, DDA has a ban on imports of U.S. sheep (due to scrapie), and goats, including semen and embryos. As of July 2001, Brazil resumed imports of fertile ostrich eggs.

Special Update on restrictions for animal and animal products from the United States due to the BSE outbreak:

Brazil's priority list of products has been reduced significantly due to the publication of Normative Instruction (IN, in Portuguese) Number 7/2004, on March 18, 2004 in Brazil's Diario Oficial (equivalent to the Federal Register in the United States). IN No.7/04 was signed by the Minister of Agriculture, Livestock, and Food Supply (MAPA).

IN No. 7/04 is the result of FAS/OAA/Brazil advocacy with the Office of Agricultural Protection (SDA/MAPA) to change old Brazilian regulation (Normative Instruction Number 15/2001), which was contrary to OIE guidelines (Article 2.313.8 of the OIE Chapter on BSE).

Article 3 of Normative Instruction No. 7/04 established that those products listed by OIE are no longer facing sanitary restrictions to be exported to Brazil. The most important products exported by the United States to Brazil under Article 3 of IN No. 7/04 are:

Bovine Semen  
Bovine Embryos  
Dairy Products (mostly whey, cheese, and lactose)  
Tallow  
Hides and Skins

Article One of Normative Instruction No. 7/04 maintains sanitary restrictions on imports of live ruminants and its by-products (beef and beef products), veterinary products containing ingredients of animal origin, and pet food. In this case, the most important products exported by the United States are:

Pet Food  
Breeding Cattle

However, Normative Instruction No. 7/04 provides a “window” (see Sole Paragraph of Article 3) for imports of “other products and inputs” through a process of risk analysis, on a case-by-case basis, according to the criteria of the Office of Agricultural Protection (SDA/MAPA). We believe this Sole Paragraph can be applied to Pet Food imports from the United States.

However, we do not believe that SDA/MAPA is ready yet to lift restrictions on live animals (breeding cattle) from the United States. The SDA/MAPA position is to lift restrictions only after OIE has a final position on this issue.

### 1.3. Department of Plant Health and Inspection Services - DDIV.

DDIV is responsible for protecting the health of plants, and to prevent the introduction into and spread of foreign pests within Brazil. In this respect, DDIV’s regulatory responsibilities are similar to those ascribed in the United States to USDA/APHIS’s Plant Protection and Quarantine (PPQ). In addition, DDIV also has the regulatory authority to enforce federal laws regarding the registration, compliance and labeling of beverages (including distilled spirits, wine, soft drinks, and juices). In this respect its regulatory responsibilities are similar to those ascribed in the United States to the Department of Treasury’s Bureau of Alcohol, Tobacco and Firearms (ATF), with the exception that DDIV provides a broader spectrum of services, including laboratory tests.



All U.S. unprocessed products of plant origin (bulk grains, fresh fruits and vegetables, nuts, and seeds) can only be exported to Brazil if accompanied by a APHIS/PPQ phytosanitary certificate. U.S. exporters should always check with the nearest PPQ office or the APHIS /PPQ home page <http://www.aphis.usda.gov> to see the latest import requirements from Brazil for unprocessed plant products because Brazil's regulations in this area are changing frequently due to the gradual harmonization of plant health regulations within MERCOSUL.

DDIV also requires that imports of wine, beer, distilled spirits and juices be registered with DDIV. In addition, the importer must also be registered with DDIV. To clear customs, these products are subject to inspection by DDIV, who will hold samples for chemical analysis. The major laws and regulations that provide DDIV's regulatory authority for domestic and imported plant products, distilled spirits, wine, beer, and juices are:

- \* Decree Number 239 of December 30, 1998.
- \* Decree 24, 144 of April 12, 1934
- \* Directives 641, 642, and 643 of October 3, 1995
- \* Directive 186 of March 21, 1996
- \* Directive 130 of April 15, 1997
- \* Directive 158 of April 16, 1997
- \* Directive 182 of November 9 1998

Note: Brazilian federal regulations can be found in the home page of the Diario Oficial (Brazil's Federal Register): <http://www.in.gov.br>

## 2. Office of Rural Development and Cooperativism (SARC)

The Office of Rural Development is responsible for enforcing regulations regarding animal and plant production, such as animal genetics, quality standards for grains, seed, fruits and vegetables, and quality and production grades and standards for pet food. In addition to rural extension responsibilities, SARC has two departments that have responsibility for inspection related activities.

### 2.1. Department of Development and Surveillance of Animal Production (DFFPA).

DFFPA is responsible for the regulatory inspection of feed for animal consumption (feeds and fodders as well as pet food), the registration of establishments producing animal semen and embryos, and the genealogical registration of live animals. In this respect it's regulatory responsibilities are similar to those ascribed by the United States to USDA/APHIS/VS, and the USDA's Grain Inspection, Packers, and Stockyards Administration (GIPSA).



U.S. companies exporting feed and fodder, pet food, live animals, semen and embryos must obtain an import permit from DFFPA. Brazilian importers of live animals must obtain a permit for import that meets the Brazilian genetic requirements for a specific breed. Brazilian importers of pet food must register the imported products with DFFPA before applying for an import permit. In all cases, the Brazilian importer must be registered with MAPA.

## 2.2. Department of Development and Surveillance of Plant Production (DFFPV).

DFFPV is responsible for the regulatory inspection and registration of all planting seeds (including biotech seeds), as well as for establishing standards for agricultural products such as grains, fruits and vegetables. In this respect its regulatory responsibilities are similar to those described in the United States to USDA/APHIS/PPQ, USDA/AMS, and USDA/GIPSA. This Department is also responsible for registration and inspection of fertilizers.

### **Ministry of Health (MS)**

#### **Anvisa**

The Ministry of Health's (MS) regulatory activities is enforced by an agency called the National Agency of Sanitary Surveillance (ANVISA). The structure of ANVISA was based on the United States' Food and Drug Administration (FDA) in that it is a semi-autonomous agency within the Ministry of Health. The ANVISA was officially created by Law 9,782 on January 26, 1999, and implemented by Decree 3,029 of April 19, 1999, and is now the scientific regulatory agency responsible for the safety of all foods (mostly processed products), except for those that fall under the regulatory authority of the Ministry of Agriculture and Food Supply (such as bulk commodities, meats, dairy, fisheries, alcoholic beverages, and feed) as discussed above.

The ANVISA is also responsible for overseeing the production and registration of drugs, food additives, medical devices, and tobacco and tobacco products. ANVISA is the coordinating agency at the national level of the Brazilian system of administrative, technical and sanitary management at ports, airports, and borders called SISPAF.

The primary function of the ANVISA is to protect the public, i.e., human health in relation to food, assessing food standards, safety, and contaminants. In addition, it is responsible for the registration of any Brazilian company or multinationals established in Brazil producing food products, such as canned products, pasta, and snacks.

Before a food product can be placed on the Brazilian market, it must be registered with ANVISA and receive a registration number which must be placed on the label of the product. The registration number for food products is valid for 5 years, while the registration of foreign or domestic firms is done on a yearly basis.

Prior to Law 9,782/99 cited above, imported food products were exempt from the registration requirement of the MS under Article 58 of Decree-Law 986 of October 21, 1969. Law 9,782/99 revokes Article 58 of Decree-Law 986 and the exemption for imported food products and established a new rule under which all foreign food products must follow the same procedures for registration as those required for domestically manufactured food items.

On March 16, 2000 ANVISA published Resolutions 22 and 23 in the *Diario Oficial* (Brazil's Federal Register), which addresses the new procedures for registration and exemption of registration of imported food products that fall under the regulatory authority of the Ministry of Health. The objectives of Resolution 22 and 23 are to provide guidance to food importers and to improve ANVISA's efficiency in coordinating public health actions on imported food products.

The products listed under ANNEX I (see below) are those food products which are exempt from product registration, while ANNEX II lists those products which have mandatory registration requirement with ANVISA. The procedures and forms for registration and exemption of registration of imported food products are the same as those for domestically produced food products.

The request for registration or exemption of registration must be done by the food importer, the local subsidiary of the exporting company, or by a legal representative of the exporter. If there is more than one importer for the same imported product, each importer must make a separate request. In the case of the subsidiary or legal representative of the exporter, one request can be done for an imported product with different brands and importers.

All imported products, additives and packaging must be in accordance with Decree-Law Number 986, of October 21, 1969 and respective regulations.

Importers of food products that are exempt from registration are still required to complete a form (ANNEX III) requesting that the product be exempt from registration. These forms must be delivered to the local office of the Ministry of Health in the state where the importer is legally based.

Importers of food products under ANNEX II must register their products and pay fees, according to the size of the company. The following fee structure is currently in force:

Description	Fee by Company Size*				
	Group I** Large	Group II** Large	Group III** Medium	Group IV** Medium	Group V** Small
Company Registration / Authorization to Sell	R\$6,000	R\$5,100	R\$4,200	R\$2,400	R\$600
Product Registration	R\$6,000	R\$5,100	R\$4,200	R\$2,400	R\$600

\*Fees are charged in local currency: the "Real" (R\$).

As of July 26, 2004 the exchange rate is US\$1.00=R\$3.00

\*\*For the purposes of this regulation the size of the company is defined as follows: Group I (Annual Income above R\$50 million); Group II (Annual Income between R\$20 million and R\$50 million); Group III (Annual income between R\$6 million and R\$20 million); Group IV (Annual income between R\$2 million to R\$6 million), and Group V (Annual Income below R\$2 million). These criteria are based on Provisional Measure Number 2,190-34, dated August 23, 2001. Brazil also defines some companies as "micro" companies, with annual income below R\$434,000. In this case, companies are exempt of above fees.

The registration for these products is valid for 5 (five) years in the entire Brazilian territory. The codes used before each product in the Annexes below are control codes used by the Ministry of Health, and should not be confused with the codes of the Harmonized Tariff System (HS).

**Annex I: imported Food Products exempt from Registration:**

Code	Description of the Product
4100115	Sugar
420038	Food and Beverages for Supplemental Nutrition
4100174	Frozen Products
4200082	Starches
4100191	Flavoring Additives
4300167	Confectionery Products
4100085	Biscuits
4100018	Coffee

4300151	Cereals and Derivatives
4300025	Teas
4100107	Colors
4300084	Vegetable Creams
4300182	Erva-Mate Tea Compounds
4100093	Prepared Seasonings
4100077	Canned Vegetables (except for Heart of Palm)
4100034	Cakes
4200071	Packaging
4300051	Erva-Mate Tea
4100042	Seasonings
4100026	Flours
4300076	Wheat Flour and/or Corn Fortified with Iron
4300164	Fruits (dried or freeze dried)
4100050	Canned Fruits
4200012	Frozen Dairy Products
4300190	Mocoto Jam
4300131	Fruit Jams
4100131	Pasta
4200098	Powders or Mixes for Food and Beverage Preparations
4100158	Vegetable Oils and Fats
4100123	Breads
4300169	Pates
4300181	Fruit Pulp
4300191	Vegetable Pulp
4300092	Preparations and Products for Seasonings
4100166	Cocoa Products/Chocolates
4200063	Coconuts Products
4100141	Baking Products
4300068	Fruit Products, Cereals and Legumes for Use in Yogurt
4100182	Soybean Food Products
4100069	Tomato Products
4300101	Snack Foods
4300163	Oilseeds
4300160	Desserts and Powders for Dessert
4300168	Soups
4300165	Vegetables (Dissected and Freeze Dried)

**Annex II: Imported Food Products With Mandatory Registration:**

Code	Description of the Product
4200047	Additives (Formulated)
4100190	Additives

4100113	Artificial Sweeteners
4200020	Mineral Water
4200030	Potable Table Water
4300164	Purified Water
4200039	Foods with Added Essential Nutrients
4300032	Functional Foods
4300033	Infant Formulas
4300083	Food for Weight Control
4300078	Food with Dietary Restrictions of Nutrients
4300086	Foods for Diets with Controlled Sweeteners
4200081	Foods for Special Diets
4300088	Foods for Pregnant and Lactating Women
4300087	Foods for Elderly People
4300085	Foods for Sport Participants
4300069	Foods of Animal Origin (only those under the Ministry of Health)
4300017	Non-Alcoholic Beverages (only those under the Ministry of Health)
4200055	Technology Coadjutants
4300162	Liquid Compounds for Consumption
4300031	Recycled Packaging
4200123	Ice
4300030	New Foods and/or New Food Ingredients
4100204	Salt
4200101	Salt - Other
4300041	Vitamin and/or Mineral Supplements
4000009	Canned Vegetable (Heart of Palm)

**Annex III: Form: Instructions**

Field A: To be filled in by the Sanitary Authority

Field B: Name of the Importer, Legal Representative of the Exporter or Subsidiary. Full address, Phone, Fax, E-mail, and Corporate Tax Number.

Field C: Information regarding the warehousing unit.

Field D: Terms of Responsibility to be signed by the importer.

Field E: Information about the product, including: validity (expiration) date of the product (Year/Month/Day); Code and Description of the Product (as per Annex I), Brand, Type of Packaging, Manufacturer (Exporter), Country of Origin, Commercial Perspective (if product is to be sold in one specific city, state, or national territory)

Note: It is common practice in Brazil to retain the services of specialized firms in registration of products within the Ministry of Agriculture and Ministry of Health. For a list of these firms, U.S. exporters should contact:

The Office of Agricultural Affairs (OAA) in Brasilia

[Agbrasil@fas.usda.gov](mailto:Agbrasil@fas.usda.gov)

The Agricultural Trade Office (ATO) in Sao Paulo

[Atosaopaulo@fas.usda.gov](mailto:Atosaopaulo@fas.usda.gov)

The major laws and regulations that provide ANVISA's regulatory authority for domestic and imported processed food products, including authorization for sale and registration of food products and risk analysis are:

- \* Decree Law 986 of October 21, 1969
- \* Law 9,782 of January 26, 1999
- \* Decree 3,029 of April 19, 1999
- \* Provisional Measure 1,912-5 of June 30, 1999
- \* Resolution 237 of July 2, 1999
- \* Resolution 22 of March 16, 2000
- \* Resolution 23 of March 16, 2000
- \* Resolution 17 of April 30, 1999
- \* Resolution 16 of April 30, 1999
- \* Resolution (RDC) 236 of December 26, 2001

Note: Brazilian federal regulations can be found in the home page of the Diario Oficial (Brazil's Federal Register): <http://www.in.gov.br> or in ANVISA's home page at <http://www.anvisa.gov.br>

## **Ministry of the Environment (MMA)**

### **Ibama**

The Brazilian Institute for the Environment and Natural Resources (IBAMA), within the Ministry of the Environment, has regulatory authority for activities that affect the environment. It is one of the key government agencies that have regulatory authority for the approval of agricultural chemicals (pesticides, herbicides, but has joint authority for this function with the Ministry of Health (which is concerned with the toxicology aspects of agricultural chemicals), and the Ministry of Agriculture, Livestock, and Food Supply (which actually provides the registration for pesticides).

IBAMA is concerned with the possible environmental impact of pesticides. In general it follows recommendations made by international standard setting organizations, such as the CODEX Alimentarius, and works closely with its U.S. counterpart, the U.S. Environmental Protection Agency (EPA).

IBAMA is also the Brazilian regulatory agency that enforces the CITIES treaty. It is the agency responsible for monitoring and enforcing activities related to the Brazilian fauna and flora. There are two regulatory rules related to these subjects in Brazil: a) Normative Instruction Number 3, dated May 27, 2003 which regulates and lists all Brazilian endangered animal species, and, b) Directive Number 37-N, dated April 3, 1992, which regulates and lists all endangered plant species. These lists can be found on IBAMA's homepage <http://www.ibama.gov.br>

### **Ministry of Development, Industry, and Foreign Trade (MDIC)**

#### **Secex**

All food products imported or exported by Brazil must be registered at the Foreign Trade Office (SECEX) of the Ministry of Development, Industry, and Foreign Trade (MDIC). This office monitors all import and exports tariffs, issues import and export licenses. In addition, SECEX is the government agency responsible for judging antidumping cases against foreign products.

Since January 1997, SECEX, the Secretariat of Federal Revenue (SRF), of the Ministry of Finance (MF), and the Brazilian Central Bank (BCB) have been responsible for import related activities such as licensing, customs clearance and exchange monitoring through the Integrated Foreign Trade System – SISCOMEX – an administrative software program with graphic interface to complete the computer-based import document. Since this system has been implemented, import and export procedures have become more transparent, allowing the GOB to adopt quick measures to minimize trade deficits and frauds. The system also enables the government to better control tax payments.

Only Brazilian registered with the Importers and Exporters Registry Office of SECEX are allowed to import. Registrations completed prior to 1997 have been entered into the SISCOMEX. New registrants are automatically added to the system upon the first import transaction. It is necessary to be registered at the SRF in order to obtain a user password to access the SISCOMEX.

For further details on SISCOMEX, please see our Export Guide (GAIN 3022).

#### **Inmetro**

Also under the MDIC is the National Institute of Metrology, Standardization, and Industrial Quality (INMETRO) which is the Brazilian agency or Inquiry Point to handle comments regarding notifications to the World Trade Organization (WTO).



INMETRO also conducts tests of domestic and imported products (industrial or food products) to check that they meet the specifications of their labels, and the safety of packaging materials.

Information on MDIC legislation and procedures can be found at and MDIC's home page <http://www.mdic.gov.br>

Note: Other Brazilian federal regulations can be found in the home page of the Diario Oficial (Brazil's Federal Register): <http://www.in.gov.br>

### **Ministry of Finance**

The Office of Federal Revenue (SRF) is responsible for collecting import duties and fees. This office works closely with SECEX (see MDIC above) in all aspects of foreign trade in Brazil.

### **Ministry of Science and Technology (MCT)**

#### **CTNBio**

The National Technical Commission on Biosafety (CNTBio), an inter-governmental Commission is under the structure of the Ministry of Science and Technology, and was formed as a result of the 1995 Brazilian Biosafety Law (Law 8,974/95 and its implementing regulation (Decree 1,752/95). CTNBio is composed primarily of scientists from government and academia, but also has representation from industry and consumer groups. Since July 2000, CTNBio is composed of 36 members.

CNTBio is the national regulatory agency responsible for developing national and international biotechnology policy in Brazil. It provides recommendations to the Government of Brazil on specific applications for product release and experimental plantings, particularly biotech products.

On December 28, 2000, the Brazilian President issued Provisional Measure Number MP 2,137 which was intended to resolve the legal problems that derived from the court battles involving the release of biotech varieties in Brazil, including court battles involving the importation of biotech corn from Argentina. MP 2,137 adds to and alters some clauses of Law 8,974/95 to more clearly define the role of CTNBio, providing CTNBio with the legal authority to issue final technical reports about the release of biotech products in Brazil, as well as redefining the functions of each Ministry within the federal government as it relates to biotech products.

The new Brazilian Government announced on February 18, 2003 the formation of a nine-member inter-ministerial working group to formulate Brazil's new policy on biotechnology, including the new functions of the CTNBio. The group developed a draft bill and the President of Brazil sent to National Congress by the end of 2003.

*Notes:*

*(a) For more information on the Biosafety Bill, please see Section F of this report;*

*(b) A Provisional Measure (MP) is an act issued by the President, under the powers and privileges granted to him by the 1998 Brazilian Constitution. It has the power of a law, until Congress gives final approval, and then becomes a law.*

The major laws and regulations that provide CNTBio's regulatory authority for domestic and imported Biotech products are:

- \*MP 2,137 of December 28, 2000
- \*Law 8,974 of January 5, 1995
- \*Decree 1,752 of December 20, 1995
- \*Provisional Measure 113 of March 26, 2003
- \*Law Number 10,688 of June 13, 2003
- \*Decree Number 4,680 of April 24, 2003

More information on CTNBio, including procedures for registration of biotech products, please check CTNBio's home page is <http://www.ctnbio.gov.br>

Note: Brazilian federal regulations can be found in the home page of the Diario Oficial (Brazil's Federal Register): <http://www.in.gov.br>

#### **Ministry of Justice (MJ)**

The Department of Consumer Protection and Defense (DPDC), within the Ministry of Justice, is the federal agency responsible for enforcing the Brazilian Consumer Code (CDC) published as Law 8,078 in 1990. The Code regulates consumer claims against adulterated food products, incorrect or misleading labels, and fraud. Each state in Brazil has an office of the Department of Consumer Protection and Defense that assists consumers directly in pursuing their rights.

The major regulations that provide the Ministry of Justice regulatory authority over domestic and imported food products, mostly in the area of food labeling and consumer rights are:

\*Law 8,078 of September 11, 1990

\*Decree 3,871 of July 18, 2001

\*Decree 4,680 of April 24, 2003

DPDC is responsible for monitoring and enforcing label requirements for biotech products in Brazil. DPDC has established a one percent tolerance limit for biotech products in foods in general. (Please see section on labeling).

For additional information on the Ministry of Justice's consumer department please check the Ministry of Justice's home page <http://www.mj.gov.br>

Note: Brazilian federal regulations can be found in the home page of the Diario Oficial (Brazil's Federal Register): <http://www.in.gov.br>

## II. LABELING REQUIREMENTS

### General Information

The Brazilian Consumer Protection Law number 8,078 of September 11, 1990, requires that all domestic and imported foods and beverages must provide the consumer with correct, precise, clear and easily readable information about the product in Portuguese.

It is common practice in Brazil for local importers, agents or distributors to affix to the foreign label a small adhesive label in Portuguese with the following information from the U.S. exporter:

Name of the Food

Country of Origin

Net Weight (in metric units)

Date of Production

Food Additives and Colors

Expiration Date (shelf life, established by the manufacturer)

Statement of Ingredients

Special Storage Instructions (when necessary)

The adhesive label must also show the identification and full address of the Brazilian importer, including its Income Tax registration number (CGC number). According to the Consumer Protection Law, the Brazilian importer is held liable in case of health risk to the consumer of an imported product. The expiration date or validity or shelf life date is very important for Brazilian consumers, and should never be overlooked for marketing purposes.

Food products other than animal origin products (meat, dairy, and fish) and biotech-derived products must be registered with the National Agency for Sanitary Surveillance (ANVISA), Ministry of Health. This is the case for most prepackaged food products listed on page 9 of this report.

ANVISA will require that the exporter present the so-called "FDA's Good Manufacturing Practices (GMP)" certification as part of the request for processing plant and label approval. The FAS office at the U.S. Embassy in Brasilia can provide U.S. companies with names and addresses of Brazilian firms that specialize in assisting with the registration of labels with the Ministry of Health.

### **Nutritional Labeling**

On March 22, 2001, the Brazilian Ministry of Health's ANVISA published Resolutions (RDC) 39 and (RDC) 40, establishing new nutritional labeling requirements for all packed foods and beverages. These nutritional labels follow the same standards of those in force in the United States. Brazilian companies had six months from March 22, 2001 to comply with this new regulation, which also applies to imported packaged foods and beverages. These resolutions entered into force on September 21, 2001.

Recently, ANVISA also published Resolution Number 100, for MERCOSUL countries, which proposes mandatory nutritional labeling for prepackaged food.

### **Labeling of Biotech Products**

On April 24, 2003 the President of the Republic published in the Diario Oficial (similar to the Federal Register) Executive Order (Decreto) Number 4,680/03 establishing the limit of one percent (see note below) for food and food ingredients destined for human or animal consumption containing or being produced with genetically modified organisms, and stated that consumers needed to be informed of the transgenic nature of the product.

Note: Previous regulation (Executive Order Number 3,871 of July 18, 2001) had established a four percent threshold, which was considered too high by environmentalists and consumer groups. Executive Order 3,871 was totally revoked by Executive Order 4,680.

The Ministry of Justice published on October 3, 2003 in their home page Public Consultation Number 1, which regulates Article 2, Paragraph One, of Executive Order Number 4,680 of April 24, 2003 regarding the symbol (Logo) for transgenic products.

Note: For further details on Public Consultation Number 1, please see GAIN 3614, dated 10/17/2003. The Brazilian government failed to notify the World Trade Organization (WTO) about this Public Consultation. In addition, the period for public comments (15 days) was not in compliance with WTO rules.

Public Consultation Number 1 received 157 written comments, of which 88 were favorable to the Logo, 54 unfavorable, and 15 related to questions and doubts.

On December 26, the Ministry of Justice published in Brazil's Diario Oficial, Directive (Portaria) Number 2,658/03 approving the regulations for the use of the transgenic logo, which basically was the same as reported in our GAIN BR3614.

As per Article Two of Directive (Portaria) 2,658/03 the new logo requirement would be effective on February 23, 2004 (60 days after the publication in the Diario Oficial of Directive 2,658/03). It applies for biotech products for both consumer and animal consumption with transgenic contents above one percent.

On February 27, 2004 The Ministry of Justice published in the Diario Oficial Directive Number 786 that extended for another 30 days the effective date of Directive 2,658/03.

Note: The new effective date was March 27, 2004

On April 2, 2004, the Civil Cabinet of the Presidency published Normative Instruction Number 1, signed by 4 cabinet ministers (Civil Cabinet, Justice, Agriculture, and Health) which established the conditions by which Directive 2,658/03 will enforce the labeling for products containing genetically modified organisms above one percent limit. In addition to the federal agencies, Normative Instruction Number 1 also provides authority to the state and municipal consumer defense officials to enforce the new labeling requirements.

#### COMMENTS:

1. Although Executive Order Number 4,680, which introduced the new threshold of one percent, was published in the Diario Oficial on April 24, 2003, it could not go into effect because Article 2, paragraph one, needed to be regulated by an additional legal instrument.
2. This was only possible through the publication of Directive Number 2,658 on December 26, 2003 that established 60-day period to come into effect (or February 23, 2004).

3. Because of the lack of coordination among the federal agencies, the Minister of Justice was forced to extend for another 30 days the effective date of Directive Number 2,658 (or March 27, 2004).
4. Finally, with the publication of Normative Instruction Number 1 on April 2, 2004 it came into effect the new Brazilian labeling requirements for biotech products came into effect.
5. Numerous deficiencies in Brazil's infrastructure for inspecting, storing and transporting soybeans present an enforcement issue; therefore, agriculture and health ministries are not yet imposing the \$6,000 fine stipulated for noncompliance.
6. However, agricultural authorities in the state of Parana have begun imposing the fine on farmers who do not label truckloads of biotech soybeans leaving their property.
7. Most farmers, and the processors who buy from them, are not sure whether their product has more than 1 percent biotech content. If Brazil steps up enforcement, most producers and processors would feel compelled to opt for biotech labeling in order to protect them from inadvertent violation of the requirement.
8. Even with these obstacles, the GOB remains committed to its policy on mandatory biotech labeling. In fact, at the recent meeting of the Codex Committee on Food Labeling, Brazil was very closely coordinating its position on the issue with the EU.

#### **Labeling of Animal Origin Products**

The Department of Animal Origin Products Inspection (DIPOA), Ministry of Agriculture, Livestock, and Food Supply (MAPA) requires that in addition to the registration of the foreign processing plant, the Brazilian importer must also file a request for the pre-registration of the foreign labels of processed meats and dairy products.

The registration process requires that the U.S. plant operators fill out a questionnaire concerning the product to be exported to Brazil. In addition to the signature of the plant operator, the government inspector at the plant must also sign questionnaires.

Directive 371/97 contains the technical regulations for labeling products of animal origin. Since January 4, 2000, only those products that have their labels pre-approved by DIPOA are allowed to enter Brazil. For additional information, U.S. exporters of meats and dairy products should instruct their importers and/or agents in Brazil to contact DIPOA at:

**DIPOA/SDA**

Ministerio da Agricultura, Pecuaria e do Abastecimento (MAPA)  
Esplanada dos Ministerios, Bloco "D", Anexo, 4 andar  
70043-900 Brasilia, DF  
Tel.: (55-61) 218-2684  
Fax: (55-61) 218-2672

**Labeling of Seafood Products**

Brazilian regulations require that U.S. companies exporting fish and seafood products to Brazil, must have their products processed in plants under supervision of a federal agency of the U.S. Government, such as the Food and Drug Administration (FDA) or with the National Marine Fisheries Service (NMFS), USDOC/NOAA. In addition to the registration of the U.S. processing plant with DIPOA, the Brazilian Government requires pre-approval of labels for seafood products.

For additional information, U.S. exporters of seafood products should instruct their importers and/or agents in Brazil to contact DIPOA at:

**DIPOA/SDA**

Ministerio da Agricultura, Pecuaria e do Abastecimento (MAPA)  
Esplanada dos Ministerios, Bloco "D", Anexo, 4 andar  
70043-900 Brasilia, DF  
Tel.: (55-61) 218-2684  
Fax: (55-61) 218-2672

**III. ADDITIVE REGULATIONS**

In general, ANVISA's requirements follow FDA regulations for food additives. For a complete list of approved food and coloring additives the U.S. exporter should contact ANVISA directly or a consulting firm in Brazil which specializes in this area. The major laws and regulations that provide regulatory framework for domestic and imported food additives are:

- \* Provisional Measure Number 69 of September 2002
- \* Law Number 9,974 of June 6, 2000
- \* Decree Number 4,074 of January 4, 2002
- \* Decree Number 55,871 of March 26, 1965
- \* Decree Number 50,040 of January 24, 1961
- \* Resolution (RDC) Number 234 of August 19, 2002
- Resolution (RDC) Number 169 of June 10, 2002

ANVISA's home page is <http://www.anvisa.gov.br>



#### IV. PACKAGING AND CONTAINER REQUIREMENTS

The Brazilian Association of Technical Rules (ABNT, in Portuguese) is the only normative forum in Brazil responsible for elaboration of technical rules (standards and specifications) for the packaging and container industries. ABNT is also a founding member of the International Organization for Standardization (ISO), the Mercosul Standardization Association (AMN), and the Pan American Commission for Technical Ruling (COPANT).

ABNT conducts the certification for consumer packaging (paper and carton boxes, plastic bags, steel sheet, aluminum cans, tetrapak, PET bottles, etc.)

ABNT also regulates the recycling of packaging and containers for food products. All manufacturers or imports shall be responsible for the recycling, disposal and removal of its package or containers, which is likely to cause serious pollution to the environment after consumption or use.

ABNT follows the international Resin Identification Code (numbering from 1 to 7) of the Society of Plastics Industry) and the Standard Recycling Symbol.

For detailed regulatory information about packaging and containers, and links to the main associations of packaging and containers, access ABNT home page at: <http://www.abnt.org.br>

The government's regulatory agency involved with the quality and safety of packaging and containers for handling food is the National Institute of Metrology, Standardization, and Industrial Quality (INMETRO), linked to the Ministry of Development, Industry, and Foreign Trade (MDIC). For additional information access INMETRO's home page at: <http://www.inmetro.gov.br>

The government's regulatory agency involved with the toxicological aspects of packaging and containers for handling food is the National Agency of Sanitary Surveillance (ANVISA), under the Ministry of Health (MS). For additional information access ANVISA's home page at: <http://www.anvisa.gov>

Brazilian food processors are very creative in packaging and have won several international prizes. Packaged retail food products from the United States and from the European Union have generally good acceptance among Brazilian consumers. U.S. exporters should be aware that Brazilian consumers prefer individual and small-size packages, due to the relatively high prices for imported products.

## V. PESTICIDES AND OTHER CONTAMINANTS

In general, Brazil adopts the international standards (Codex Alimentarius) for tolerances for pesticides, herbicides, and fungicides used in fumigation of agricultural products. These tolerance level regulations apply to all chemically treated products produced in Brazil or imported that are intended for human and animal consumption.

Regulatory authority for the registration of agricultural chemicals in Brazil is divided among three party committee (Agriculture, Health, and Environment) of the federal government. The Ministry of Agriculture, Livestock, and Food Supply (MAPA) is the initial contact point for the petition for registration. MAPA will then forward the petition to the Ministry of the Environment that will assess the possible environmental impact of that specific chemical. The petition is then sent to the Ministry of Health which will assess the toxicology aspects of the product. Finally, the petition is returned to the MAPA for final approval and registration.

U.S. exporters can obtain a list of approved pesticides by writing to:

DDIV/SDA

Ministerio da Agricultura e do Abastecimento

Esplanada dos Ministerios, Bloco D, Anexo, 3 andar

70403-900 Brasilia, DF

Tel.: (55-61) 218-2172

Fax (55-61) 224-3874

The major laws and regulations that provide regulatory framework for domestic and imported pesticides and other contaminants are:

- \* Resolution RDC Number 175 of July 8, 2003
- \* Resolution RDC 274 of October 15, 2002
- \* Decree Number 4,074 of January 4, 2002
- \* Law Number 9,974 of June 2000
- \* Directive Number 685 of August 27, 1998
- \* Law Number 7,802 of July 11, 1989

## VI. OTHER REGULATIONS AND REQUIREMENTS

### Inspection Requirements for Meat, Dairy, and Seafood Products

Brazilian regulations require U.S. companies exporting products of animal origin to Brazil to have their products (beef, pork, powder milk, whey, lactose, cheese, and seafood) processed in plants in the United States that are federally inspected. Brazilian inspection officials will not register U.S. plants on the basis of state inspection or products from uninspected facilities.

The only federal agency eligible to approve U.S. processing meat plants is the Food Safety and Inspection Service (FSIS), U.S. Department of Agriculture. The only federal agency eligible to approve U.S. processing dairy plants to export to Brazil is the Agricultural Marketing Services (AMS), U.S.

Department of Agriculture or the Food and Drug Administration (FDA). The U.S. exporter must have the processing plant included in AMS's list of U.S. Dairy Plants Surveyed and Approved for USDA Grading Service or have the Central File Number under FDA. The same procedure applies for exports of U.S. seafood. The U.S. plant must be inspected by either NOAA/NMFS or FDA before exporting to Brazil, and be included on DIPOA's list. The U.S. exporter must request that the processing plant be included in the list of approved U.S. plants to export to Brazil. The Department of Animal Origin Products Inspection Service (DIPOA), under the Ministry of Agriculture, Livestock, and Food Supply (MAPA), issues the authorization. The request for registration of the U.S. plant with DIPOA must be done through the FAS office in the U.S. Embassy in Brasilia. The U.S. exporter must provide the FAS office in Brasilia, by fax, the following information:

- (1) Full name and address of your plant(s), including telephone, fax, and contact person;
- (2) Plant registration number with the Food Safety Inspection Service (FSIS), U.S. Department of Agriculture (USDA) for meat products or plant registration number with the Agricultural Marketing Service (AMS) or the central file number from the Food and Drug Administration (FDA) for dairy products, or the central file number from FDA or Plant registration number with NOAA/NMFS for seafood products;
- (3) Description of the product to be exported to Brazil: fresh/frozen beef, beef products, beef offals, pork, pork products, prepared foods, milk and milk products (cheese, whey, butter, butter oil, lactose), and seafood products (in this case provide the scientific name of the fish in Latin and how the product will be shipped to Brazil).

DIPOA's approval process can take up to one month.

**IMPORTANT NOTES:**

(1) Samples and mail orders of products of animal origin shipped to Brazil for trade shows or market testing must come from plants approved by DIPOA officials.

(2) The National Agency of Sanitary Surveillance (ANVISA), Ministry of Health, is responsible for the registration of ice cream. It follows the same procedures as those for registration of processed foods, including the payment of a registration fee for the registration of the company as well as the specific product. (See Ministry of Health Section above.)

(3) As of April 16, 2002, DIPOA resumed registration of new U.S. meat and dairy plants to exports their products to Brazil, after a 3 year ban.

(4) DIPOA officials do not register U.S. poultry plants for exports of poultry products to Brazil due the lack of reciprocity.

**Inspection Requirements for Plant Products**

All U.S. unprocessed products of plant origin (bulk grains, fresh fruits and vegetables, nuts, and seeds) can only be exported to Brazil if accompanied by a APHIS/PPQ phytosanitary certificate. Frozen fruits and vegetables do not need a phytosanitary certificate. U.S. exporters should always check the nearest PPQ office or the APHIS home page to see the latest import requirements and to see if there is a need to conduct a PRA (Pest Risk Assessment) of the product before exporting to Brazil.

**Pest Risk Assessments**

On March 27, 2002, the Brazilian Government published Normative Instruction no. 34, which requires Pest Risk Assessments (PRAs) for each species from every country of origin within 180 days (ending November 27, 2002). Given the many changes occurring in this sector at this time and the ongoing regional harmonization of phytosanitary requirements as well as specific Brazilian issues of concern, U.S. exporters should check with APHIS/Brasilia for additional information on the status of Brazilian phytosanitary import requirements.

The new Normative Instruction no. 59 of November 21, 2002 establishes the procedures for submitting PRAs to the Brazilian Government. It clarifies the pest risk analysis to be followed, and specifies that "documentation be submitted in Portuguese, and be reviewed by USDA/APHIS/PPQ."

U.S. exporters need to be aware that PRAs will need to be done on third-country origin plant products that are re-exported from the United States to Brazil, with information provided by the country-of-origin.

Normative Instruction Number 60 of November 21, 2002 allows the importation of plant products traditionally imported by Brazil while the PRA is under review by MAPA/DDIV.

Questions about specific Brazilian import requirements can also be directed to APHIS/PPQ at the following address:

Export Certification Unit  
Plant Protection and Quarantine (PPQ)  
Animal and Plant Health Inspection Service (APHIS)  
U.S. Department of Agriculture  
4700 River Road Unit 139  
Riverdale, MD 20737-1236  
Tel: (301) 734-8537  
Fax: (301) 734-5786

#### **Inspection Requirements for Animal Genetics**

The Department of Animal Health (DDA), Ministry of Agriculture, Livestock, and Food Supply (MAPA) is responsible for issuing animal health requirements for imports of live animals, semen and embryos. In addition, the Office of Rural Development and Cooperatives (SARC) must also issue the genetic requirements/standards for each breed of animal.

Before exporting live animals, semen or embryos to Brazil, the U.S. exporter should contact APHIS/VS at the following address:

National Center for Import and Export Animals Program  
Veterinary Services  
Animal and Plant Health Inspection Service (APHIS)  
U.S. Department of Agriculture  
4700 River Road Unit 39  
Riverdale, MD 20737-1231  
Tel.: (301) 734-7511  
Fax: (301) 734-6402

#### **Inspection Requirements for Animal Feed**

U.S. exporters of animal feed and fodder, including pet food, must be registered with the Department of Development and Surveillance of Plant Production (DFFPV), Office of Rural Development and Cooperativism (SARC), Ministry of Agriculture, Livestock, and Food Supply (MAPA).

The U.S. exporter of animal feed should first obtain an importer (or a legal representative) in Brazil who will file the request for registration of the imported product with DFFPV/MAPA. The importer must also be registered with the Ministry of Agriculture before submitting a request for registration. A comprehensive questionnaire must be filled out including label information.

### **Veterinary Biologics**

The importation of veterinary Biologics, such as vaccines, antiserums, and diagnostic test kits, are subject to prior registration with the Department of Animal Health (DDA), Ministry of Agriculture, Livestock, and Food Supply (MAPA). DDA does not register growth promotants (hormone) for beef cattle, but does for dairy cattle.

The U.S. exporter of veterinary biologics should first obtain an importer (or a legal representative) in Brazil who will file the request for registration of the imported product with DDA/MAPA. The importer must also be registered with the Ministry of Agriculture before submitting his request for registration. A comprehensive questionnaire must be filled out including label information.

### **Alcoholic and Other Beverages**

The Department of Plant Health and Inspection Service (DDIV), Ministry of Agriculture, Livestock, and Food Supply (MAPA) has the regulatory authority to enforce federal laws regarding the registration, and labeling of beer, distilled spirits, wine, soft drinks, and juices. In this respect, its regulatory responsibilities are similar to those ascribed in the United States to the Department of Treasury's Bureau of Alcohol, Tobacco, and Firearms (ATF), with the exception that DDIV provides a broader spectrum of services, including laboratory tests.

The major regulation for alcoholic and beverage products, both domestic or imported, is:

\* Decree Number 4,072 of January 3, 2002

## **VII. OTHER SPECIFIC STANDARDS**

### **Endangered Species**

The import and export of animals and plants into Brazil that are covered by the Convention on the International Trade in Endangered Species of Wild Flora and Fauna (CITES) fall under the regulatory responsibility of the Ministry of the Environment. A specific authorization is needed to enter or leave the country with animals and plants protected under the CITES.

The Ministry of the Environment published on May 22, 2003 the new list of Brazilian endangered species.

The list is available in the following site:

<http://www.mma.gov.br/port/sbf/fauna/index.cfm>

### **Supplemental, Dietary, and Functional Foods**

The import of infant formula, dietary, and supplemental foods are under the responsibility of the National Agency of Sanitary Surveillance (ANVISA), Ministry of Health. It follows the same procedures as those for registration of processed foods, including the payment of a registration fee for the registration of the company as well as the specific product (See Ministry of Health Section above).

The major regulations that provide regulatory framework for domestic and imported functional and other specialty foods under the Ministry of Health's ANVISA are:

- \* Resolution Number 19 of April 30, 1999
- \* Resolution 18 of April 30, 1999

### **Organic Foods**

Organic farming is growing rapidly in Brazil. Growth is estimated at 20 percent per year, and commercial production is still limited mostly to grains and vegetables, although it is increasing in the meat and dairy sectors as well. The growth in organics in Brazil has been recently boosted by the large interest of the Brazilian supermarkets in buying organic products. The country has about 1,200 certified farmers and two private institutions with the authority to certify organic products. There are no official trade statistics about organic products, either for imports or exports.

The rapid growth of organic farming in Brazil has prompted the Brazilian government to regulate the sector. On May 19, 1999, the Minister of Agriculture, Livestock, and Food Supply (MAPA) published in the Diario Oficial (Brazil's Federal Register) Normative Instruction Number 7, which contains the standards for production, classification, processing, packaging, imports, distribution, identification, and certification of the quality of organic products, of both animal and plant origin.

Both domestic and imported organic products must be labeled with the term "organic product" and the name and registration number of the certifying organization. For bulk products, a "certificate of organic quality" must accompany the shipment. The Office of Agricultural Protection (SDA) of the Ministry of Agriculture, Livestock, and Food Supply (MAPA) has the authority regarding import approval of organic products.



A draft bill number 014 is currently in the National Congress, which will provide the new legal framework for organic foods in Brazil, including certification. The bill has passed the Senate, but still needs to be reviewed by the House.

### **Biotech Products**

The National Technical Commission of Biosafety (CTNBio) is an inter-governmental commission that is based within the Ministry of Science and Technology, and was formed as a result of the 1995 Brazilian Biosafety Law (Law 8,974/95 of January 6, 1995). CNTBio is the national regulatory agency responsible for developing national and international biotechnology policy in Brazil. It provides recommendations to the Government of Brazil on specific applications for product release and experimental plantings of biotech products.

Brazil's law 8,974/95 prohibits the entry of genetically modified organisms in Brazil without prior approval. The law does not distinguish between biotech products for planting and release into the environment and those for processing into animal feed or human consumption.

CTNBio's decision to release Round up Ready soybeans for commercial planting in Brazil has been suspended by an injunction of a federal judge. The request for the injunction was made by a Brazilian consumer protection group (IDEC) and Greenpeace.

As of On June 28, 2004 a three-judge panel of the Regional Federal Court (TRF in Portuguese), decided on the merits of a previous rule by the 6<sup>th</sup> Federal Circuit ("lower court") on Monsanto's Round Up Ready Soybean (RRS) case. The final panel decision (two votes against one) ruled as follows:

- a) In favor of the legality (authority) of the National Technical Commission on Biosafety (CTNBio) to waive environmental impact studies and reports for biotech products. The lower court had ruled in 1999 that CTNBio had no authority to waive such environmental reports and ruled in favor of the Consumer Protection Institute (IDEC) of Sao Paulo and Greenpeace who filed the court case against Monsanto.
- b) In favor of the lower court case that ruled against Monsanto and required environmental study reports for their biotech product (RRS).

Monsanto already declared they will appeal against the decision of the court panel that requires environmental study reports for its RRS, and IDEC also declared they will appeal against the court panel for recognizing the authority

of CTNBio for authorizing biotech products for commercial use. IDEC believes that CTNBio has only a "consultative" power, and not a deliberative power to approve the final use of biotech products. The appeal by both parties will be to the Superior Justice Court (TSJ, in Portuguese).

The TRF final decision (Attachment 1) is a victory for the Brazilian scientists that are lobbying for CTNBio to hold its authority to approve biotech products, without environmental study reports and a loss to Monsanto that continues to have its RRS prohibited by the courts, except for the 2004/05 crop year, which plantings are under the terms of law 10,814/03.

CTNBio has not publicly released any statement until its board meeting within 15 days. There are 15 biotech products pending approval by CTNBio.

Previous authorizations of CTNBio for release of Bt corn imported from Argentina for animal feed have also resulted in judicial battles among Brazilian government agencies and the judiciary. Although several shipments were unloaded in the Port of Recife, Brazilian importers of corn (mostly poultry and swine producers and processors in the Northeast) are reluctant to import corn without assurances that it is non-biotech. Consumer groups have appealed to Brazilian courts against CTNBio's decision on Bt corn.

On February 21, 2003 the Brazilian government issued Decree Number 4,602 creating a nine-member inter-ministerial working group to produce official recommendations for the Government stance on biotech products.

As a result of the recommendations of the nine-member inter-ministerial working group and in the absence of a final court ruling, the President of Brazil issued two Provisional Measures (both later voted into law by Congress) that legalized the 2002/03-and 2003/04-biotech soybean crops. For the current 2003/04-soybean crop, the measure requires farmers who planted biotech soybeans to certify that no biotech soybean seed will be saved for the next crop (2004/05).

On October 31, 2003, the GOB released a new draft of the Biosafety law. The content of this draft law was bitterly disputed between the Agricultural Minister, who is supportive of biotechnology, and the Environment Minister, who is strongly opposed to the issue. The draft law establishes a complicated mechanism for approval of biotech products by creating a national council attached to the Presidency that would consider political and economic factors, as well as scientific reports, before approving biotech research or planting. The law also authorizes the legal production and commercialization of biotech soybeans through the 2004/05-crop year. The Brazilian Chamber of Deputies passed the draft law on February 5, 2004. However, there are still many

unresolved questions and points of contention, which could delay Senate approval until the end of the year.

On June 2003, FAS sponsored a Brazilian Congressional biotechnology orientation trip to the United States, where they met with the U.S. House Agriculture Committee, U.S. regulators, USTR, Under Secretary Dr. Penn and Monsanto. The event provided a much-needed and timely infusion of science-based discussion on biotechnology as the Brazilian Administration was preparing its draft Biosafety Law.

With the official admission in 2003 that Brazil was producing and exporting Round Up Ready soybeans, Monsanto began to collect royalties from producers of Roundup Ready soybeans in Rio Grande do Sul and Santa Catarina in April 2004. Reportedly, about 80 percent of Rio Grande do Sul's soybean production is estimated to be Roundup Ready, so Monsanto is expected to collect R\$ 44 million (about USD 15 million) in royalties. The Roundup Ready soy crop in Santa Catarina is very small.

Brazil is a Party to the Biosafety Protocol. At the first meeting of the Parties in February 2004, Brazil made some strong interventions to advance the interests of trade and agriculture that were met with significant pushback from others Parties. This was surprising given Brazil's domestic situation on biotechnology and the strength of environmental interests. The United States has avoided approaching Brazil directly on these issues due to concern that the tone of our overall trading relationship would be counterproductive. However, the United States has been actively supporting Argentina's efforts to more directly engage Brazil on commodity issues where the United States and Argentina have shared views.

Brazil is a third party to the U.S./Canadian/Argentine WTO case against the EU on its biotech moratorium. At the recent panel meeting in Geneva to hear oral arguments on the case, Brazil did not file a brief or make a substantive oral statement, but it did indicate that it had a systematic interest in the outcome of the case. At the panel meeting, the EU indicated that it would be putting questions to all the third parties, which third parties can elect to answer or not. Given recent close coordination between the EU on biotech labeling issues and the reluctance to approve biotech products, it is likely any Brazilian responses would support the EU position.

Note: Please refer to our reports GAIN BR 4612, 4613 and 4614 for an update of biotech issues in Brazil.

## VIII. COPYRIGHT/TRADEMARK LAWS

### Inpi

The National Institute of Industrial Property (INPI) is a federal agency created in 1970, and linked to the Ministry of Development, Industry, and Foreign Trade (MDIC) responsible for protecting patents, trademarks, and copyrights. INPI is currently regulated by Law 9,279/96 (Industrial Property Law).

Registration of a trademark in Brazil may be obtained by filing an application letter to INPI. Once registered, the validity of the registration is for 20 years.

According to trade specialists, despite recent improvements, Brazil continues to fall short in providing adequate and effective protection of Intellectual Property Rights (IPR). Although Brazil is one of the largest markets globally for legitimate copyrighted products, it is also one of the world's largest pirate markets.

For general information on legislation, regulations, application for copyrights, patents, and trademarks, please access INPI home page at:  
<http://www.inpi.gov.br>

## IX. IMPORT PROCEDURES

### Documentation and Merchandise Entry

After you establish your business relationship, and negotiate your sale, your Brazilian importer, or agent follows the following basic steps:

- a) The U.S. exporter must supply the representative in Brazil with a *Pro forma* invoice for the product (s) to be exported to Brazil;
- b) The Brazilian representative files an application for an import permit for the specific transaction with the Foreign Trade Office (SECEX);
- c) In case of some agricultural products (plants, seeds); animal genetics (live animals, semen, embryos) and products of animal origin (meats, dairy) the importer must check with the Ministry of Agriculture, Livestock, and Food Supply (MAPA) for the import requirements for that specific product. For instance, to import beef, the U.S. plant must be registered with the Department of Animal Origin Inspection Service (DIPOA), and have labels pre-approved by DIPOA. Most of these transactions are done on-line through the Automatic Import Licensing System called SISCOMEX;

d) Once the application for the import of the shipment is approved by SECEX, the importer notifies the U.S. supplier to ship the product(s);

e) The U.S. exporter should send all shipment documents (Bill of Lading, etc.) and the commercial invoice along with the product;

Note: For some products of animal origin and animal genetics, the Ministry of Agriculture, Livestock, and Food Supply (MAPA) requests that the export certificate be certified (stamped) by a Brazilian Consulate in the United States.

f) The importer arranges for a licensed customs expeditor to clear the goods and pay customs duties and other taxes (typically the ICMS (value-added) tax, and,

g) A copy of the import license and the paid customs declaration are sent to the bank to complete the foreign exchange transaction.

Notes:

(1) Before shipping an exporter should ask that the importer open an irrevocable and confirmed Letter of Credit.

(2) For further details on exports of food products to Brazil, please see our Export Guide (GAIN 3022).

### **Establishing a Business Relationship**

All the customary import channels exist in Brazil: agents, distributors, brokers, wholesalers, specialty import houses, trading companies, subsidiaries, and branches of foreign firms, among others. The best way to do business in Brazil is to establish a business relationship with or through one of these established channels. As in other countries, the selection of the importer requires careful consideration. A unique aspect of the Brazilian market is that a single importer may not be able to cover the entire country adequately, and there is no need to grant exclusive rights.

Potential U.S. food exporters to Brazil should take into consideration the following factors while establishing a business relationship:

a) Although Brazil is of vast geographic size, the majority of importers are located in Sao Paulo and in Rio de Janeiro, and to a lesser extent in Belo Horizonte, Curitiba, Porto Alegre, Salvador, Recife, and Fortaleza.

b) Participation in trade shows is encouraged. The major shows include: the National Supermarket Convention and Exhibition (ABRAS show), held annually in September in Rio de Janeiro; the Sao Paulo Supermarket Convention and Exhibition (APAS Show), held in May in Sao Paulo, and the International Food Show (FISPAL), held in June in Sao Paulo. FAS's Agricultural Trade Office (ATO) in Sao Paulo maintains a list of trade shows in Brazil that target specific products and sectors.

c) A well-qualified Brazilian importer should have an office in one of the cities mentioned above and must be registered with the Brazilian Foreign Trade Office (DECEX) of the Ministry of Development, Industry and Commerce (MDIC). To operate in Brazil, the importer must also be registered with the Ministry of Finance (similar to the Treasury Department), and hold a registration number called CNPJ. See GAIN 3022 for further details.

d) Import duties and taxes. Since 1990, Brazil eliminated a number of non-tariff barriers to imports, and lowered most import duties on commodities and foods. Import duties vary from 8 to 14% for most bulk agricultural products and 14 to 23% on highly processed food products. Today, Brazil, together with its MERCOSUL partners (Argentina, Uruguay, and Paraguay), applies the MERCOSUL Common External Tariff (CXT). In addition, Chile and Bolivia, as associate members of MERCOSUL, enjoy preferential import tariffs.

**APPENDIX I – GOVERNMENT REGULATORY AGENCY CONTACTS**

Office of Agricultural Protection (SDA)  
Ministry of Agriculture, Livestock, and Food  
Supply (MAPA)  
Esplanada dos Ministerios, Bloco D  
Anexo B, 4 Andar, Sala 406  
Brasilia, DF 70043-900  
Phone: (55-61)218-2314/15  
FAX: (55-61) 224-3996 or 218-2316  
Internet site: <http://www.agricultura.gov.br>

Brazilian Environment Institute (IBAMA)  
SAIN - Av. L 4 Norte  
70800-200 Brasilia, DF  
Phone: (55-61) 226-8221  
Fax: 322-1058  
Internet site: <http://www.ibama.gov.br>

Office of Rural Development and  
Cooperativism (SARC)  
Ministry of Agriculture, Livestock, and  
and Food Supply (MAPA)  
Esplanada dos Ministerios, Bloco D, 3 Andar  
Sala 304  
Brasilia, DF 70043-900  
Phone: (55-61) 321-3594  
Fax: (55-61) 321-4524  
Internet site: <http://www.agricultura.gov.br>

Ministry of Science & Tecnology (MCT)  
Esplanada dos Ministerios, Bloco E  
70067-900 Brasilia, DF  
Phone: (55-61) 321-8886  
Fax: (55-61) 225-7496  
Internet site: <http://www.mct.gov.br>

Agency of Sanitary Surveillance (ANVISA)  
Ministry of Health  
Esplanada dos Ministerios, Bloco G  
70058-900 Brasilia, DF  
Phone: (55-61) 315-2343  
Fax: (55-61) 225-6056  
Internet site: <http://www.saude.gov.br>

Ministry of Justice  
Esplanada dos Ministerios, Bloco T  
70064-900 Brasilia, DF  
Phone: (55-11) 224-0954  
Fax: (55-61) 322-6817  
Internet site: <http://www.mj.gov.br>

Ministry of Development, Industry and  
Foreign Trade (MDIC)  
Esplanada dos Ministerios, Bloco J  
70056-900 Brasilia, DF  
Phone: (55-61) 329-7000  
Fax: (55-61) 329-7230  
Internet site: <http://www.mdic.gov.br>

Brazilian Customs (Receita Federal)  
Ministry of Finance  
Esplanada dos Ministerios, Bloco P  
70048-900 Brasilia, DF  
Phone: (55-61) 412-3000  
Fax: (55-61) 412-1721  
Internet site: <http://www.fazenda.gov.br>



**APPENDIX II – OTHER IMPORT SPECIALIST CONTACTS**

Foodstaff (Consultant for food registration)  
Alameda Guainumbis, 1089

04067-002 Sao Paulo, SP  
Phone: (55-11) 5561-3276  
Fax (55-11) 535-3976  
Internet site: <http://www.foodstaff.com.br>

American Chamber of Commerce Sao Paulo  
Rua Alexandre Dumas, 1976  
04717-004 Sao Paulo, SP  
Phone: (55-11) 246-9199  
Fax: (55-11) 246-9080  
Internet site: <http://www.amcham.com.br>

Brazilian Assoc. of Food Industries (ABIA)  
Av. Brigadeiro Faria Lima, 2003, 11 Andar  
01451-001 Sao Paulo, SP  
Phone: (55-11) 814-6688  
Fax: (55-11) 814-6688  
Internet site: <http://www.abia.com.br>

Brazilian Association of  
Supermarkets (ABRAS)  
Av. Diogenes Ribeiro de Lima, 2872  
05083-901 Sao Paulo, SP  
Phone: (55-11) 838-4500  
Fax: (55-11) 837-9933  
Internet site:  
<http://www.abrasnet.com.br>

FoodNet (FISPAL Food Show)  
Rua Min. Nelson Hungria, 239/12  
05690-050 Sao Paulo, SP  
Phone: (55-11) 844-9111  
Fax: (55-11) 844-8893  
Internet site: <http://www.foodnet.com.br>

For additional information on this report, please contact one of the following FAS offices in Brazil:

Office of Agricultural Affairs (OAA)  
American Embassy, Brasilia  
Av. das Nacoes, Quadra 801, lote 3  
70403-900 Brasilia, DF  
Phone: (55-61) 312-7101  
Fax: (55-61) 312-7659  
[Agbrasil@fas.usda.gov](mailto:Agbrasil@fas.usda.gov)

Agricultural Trade Office (ATO)  
Rua Henri Dummont, 700  
01418-200 Sao Paulo, SP  
Phone: (55-11) 5186-7400  
Fax: (55-11) 5186-7499  
E-mail: [Atobrazil@usdabrazil.org.br](mailto:Atobrazil@usdabrazil.org.br)  
<http://www.usdabrazil.org.br>